

## **EXHIBIT A**

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ENDORSED  
FILED  
San Francisco County Superior Court

FEB 14 2007

CASE MANAGEMENT CONFERENCE SET  
EXCERPT BY CHRISTINA E. BAUTISTA  
JUL 20 2007 - 9 AM Deputy Clerk

DEPARTMENT 211

6 SUPERIOR COURT OF CALIFORNIA

7 COUNTY OF SAN FRANCISCO

8 MELONEY WRIGHT and DONNY  
WRIGHT, wife and husband; DANYELE  
9 BACON, a single woman; DIANA BURK, a  
single woman; TINA LEIPHART, a single  
10 woman; NUBIA FLORES, a single woman;  
MOLLY KIRKPATRICK, a single woman;  
11 REYNALDA ALVARADO, a single  
woman; GAYLE ANDERSON, a single  
12 woman; VERONIQUE PETERS and  
DONNY PETERS, wife and husband;  
13 LAKEYA BASKOM, a single woman;  
TIFFANY LILLIE, a single woman, and  
14 LORRAINE FONTANILLA-WEBBER, on  
behalf of her minor daughter, ASHLEY  
15 WEBBER,

No. CGC07-460481

COMPLAINT FOR DAMAGES

and

CGC07-460481  
DEMAND FOR JURY TRIAL

16 Plaintiffs,

17 vs.

18 ORTHO-MCNEIL CORPORATION, a  
foreign corporation; JOHNSON &  
19 JOHNSON, a foreign corporation;  
JOHNSON & JOHNSON SERVICES,  
20 INC., a foreign corporation; JOHNSON &  
JOHNSON HEALTH CARE SYSTEMS,  
21 INC., a foreign corporation; JOHNSON &  
JOHNSON RESEARCH &  
22 DEVELOPMENT, LLC., a foreign  
corporation; JOHNSON & JOHNSON  
23 CONSUMER COMPANIES, INC., a  
foreign corporation; MCKESSON  
24 CORPORATION, a Delaware corporation;  
ALZA CORPORATION, a California  
25 corporation aka ALZA DEVELOPMENT  
aka ALZA INTERNATIONAL, INC., and  
26 DOES 1-50,

1  
Defendants.  
2

3 For their Complaint against the defendants, Plaintiffs allege:

4 PARTIES

- 5 1. Plaintiff MELONEY WRIGHT and DONNY WRIGHT are wife and husband  
and citizens of the State of California. Meloney Wright was prescribed and used Ortho  
6 Evra™.
- 7 2. Plaintiff DANYELE BACON is a citizen of the State of California, and was  
prescribed and used Ortho Evra™.
- 8 3. Plaintiff DIANA BURK is a citizen of the State of Arizona, and was prescribed  
and used Ortho Evra™.
- 9 4. Plaintiff TINA LEIPHART is a citizen of the State of Arizona, and was  
prescribed and used Ortho Evra™.
- 10 5. Plaintiff NUBIA FLORES is a citizen of the State of Arizona, and was  
prescribed and used Ortho Evra™.
- 11 6. Plaintiff MOLLY KIRKPATRICK is a citizen of the State of Arizona, and was  
prescribed and used Ortho Evra™.
- 12 7. Plaintiff REYNALDA ALVARADO is a citizen of the State of Arizona, and  
was prescribed and used Ortho Evra™.
- 13 8. Plaintiff GAYLE ANDERSON is a citizen of the State of Iowa, and was  
prescribed and used Ortho Evra™.
- 14 9. Plaintiff LAKEYA BASKOM is a citizen of the State of Arizona, and was  
prescribed and used Ortho Evra™.
- 15 10. Plaintiff TIFFANY LILLIE is a citizen of the State of Arizona, and was  
prescribed and used Ortho Evra™.
- 16 11. Plaintiffs VERONIQUE PETERS and DONNYPETERS are wife and husband

1 and citizens of the State of Arizona, and Plaintiff Veronique Peters was prescribed and used  
2 Ortho Evra™.

3 12. Plaintiff LORRAINE FONTANILLA-WEBBER is a citizen of the State of  
4 Arizona, and brings this action on behalf of her minor daughter, ASHLEY WEBBER, who  
5 was prescribed and used Ortho Evra™.

6 13. Johnson & Johnson (hereafter, "Johnson & Johnson"), is a corporation  
7 organized and existing under the laws of the State of New Jersey, with its principal place of  
8 business in New Jersey. Johnson & Johnson was and is authorized to do business in the State  
9 of California and was engaged in substantial commerce and business activity in the County  
10 of San Francisco.

11 14. Johnson & Johnson, a foreign corporation; Johnson & Johnson Services, Inc.,  
12 Johnson & Johnson Health Care Systems, Inc., Johnson & Johnson Research &  
13 Development, LLC., and Johnson & Johnson Consumer Companies, Inc., are divisions of  
14 Johnson & Johnson, are either organized under the laws of California, New Jersey or  
15 Delaware, and are named herein as other companies very closely related to Johnson &  
16 Johnson, and who may also have been involved in the design, promotion, sale, and/or  
17 distribution of Ortho Evra™, and will be referred to collectively as "Johnson & Johnson",  
18 until such time as their involvement becomes more evident.

19 15. Defendant McKesson Corporation (hereafter, "McKesson") was and is a  
20 corporation organized and existing under the laws of the State of Delaware, with its principal  
21 place of business in San Francisco, California. McKesson was and is authorized to do  
22 business in the State of California and was engaged in substantial commerce and business  
23 activity in the County of San Francisco.

24 16. Defendant Alza Corporation (hereafter, "Alza") was and is a corporation  
25 organized and existing under the laws of the State of Delaware, with its principal place of  
26 business in San Jose, California, was and is authorized to do business in the State of

1 California, is a subsidiary corporation of Defendant Johnson & Johnson and was engaged in  
2 substantial commerce and business activity in the County of San Francisco.

3       17. Ortho-McNeil (hereafter, "Ortho-McNeil") is a corporation organized and  
4 existing under the laws of the State of New Jersey, with its principal place of business in  
5 New Jersey, was and is authorized to do business in the State of California, is a subsidiary  
6 corporation of Defendant Johnson & Johnson, and was engaged in substantial commerce and  
7 business activity in the County of San Francisco.

8       18. The true names or capacities, whether individual, corporate, or otherwise, of  
9 Defendants Does 1-50, are unknown to Plaintiffs who therefore sue said Defendants by such  
10 fictitious names. Plaintiffs believe and allege that each of the Defendants designated herein  
11 by fictitious names is in some manner legally responsible for the events and happenings  
12 herein referred to and proximately caused foreseeable damages to Plaintiffs as alleged herein.

13       19. At all times herein mentioned, "Defendants" include all named Defendants  
14 herein as well as Defendants Does 1-50.

15       20. At all relevant times Defendants, through their agents, servants, employees and  
16 apparent agents, were the designers, manufacturers, marketers, distributors and/or sellers of  
17 Ortho Evra™, which is the only birth control drug which is delivered by a transdermal patch.

18       21. Defendants, either directly or through their agents, apparent agents, servants  
19 or employees, at all relevant times, sold and distributed Ortho Evra™ in the States of  
20 California, Arizona, Mississippi, Iowa, and in other states and foreign countries.

21       22. Defendants derive substantial revenue from pharmaceutical products used or  
22 consumed in the State of California.

23       23. Defendants expected or should have expected, that their business activities  
24 could or would have consequences within the State of California, as well as throughout the  
25 United States.

26       24. Plaintiffs bring this action to recover damages, restitution, refunds, loss of

1 consortium and/or for equitable, injunctive and declaratory relief against Defendants.

2 25. Defendants placed Ortho Evra™ into the stream of worldwide commerce and  
3 interstate commerce in the United States. It did so without adequate testing and with no  
4 warning that the drug carried with it a risk of causing thromboembolic and myocardial  
5 events, far in excess of those risks associated with other forms of birth control.

6 26. Plaintiffs need continued medical monitoring to prevent or mitigate the future  
7 onset of thromboembolic and myocardial events which have already manifested.

8 27. Defendants did directly and/or through authorized agents, sell and/or distribute  
9 Ortho Evra™ to each individual Plaintiff.

## **SUMMARY OF THE CASE**

11        28. Defendants, either directly or through their agents, apparent agents, servants  
12 or employees, designed, manufactured, marketed, advertised, distributed and sold Ortho  
13 Evra™ as the only transdermal delivery birth control device.

14        29. As a result of the defective nature of Ortho Evra™, persons who were  
15 prescribed and used Ortho Evra™, including Plaintiffs, have suffered and may continue to  
16 suffer severe and permanent personal injuries, including, but not limited to,  
17 thromboembolic and myocardial events.

18 30. Defendants concealed and continue to conceal their knowledge of Ortho  
19 Evra™'s unreasonably dangerous risks from Plaintiffs, other consumers, and the medical  
20 community.

21 31. Defendants failed to conduct adequate and sufficient post marketing  
22 surveillance of Ortho Evra™ after it began marketing, advertising, distributing, and selling  
23 the drug.

24 32. As a result of Defendants' actions and inaction, Plaintiffs were injured due to  
25 use of Ortho Evra™, which has caused and will continue to cause Plaintiffs various injuries  
26 and damages. Plaintiffs accordingly seek compensatory damages.

## **FACTUAL BACKGROUND**

2 33. At all relevant times Defendants were responsible for, or involved in,  
3 designing, manufacturing, marketing, advertising, distributing, and selling Ortho Evra™.

4       34. In 2002, the United States Food and Drug Administration (“FDA”) approved  
5 Ortho Evra™ as a transdermal delivery system of hormone replacement birth control, but that  
6 Defendants intentionally/recklessly and/or negligently, did not give the FDA complete and  
7 adequate information upon which the FDA could have made a complete and adequate  
8 evaluation of this drug, and had the FDA been given such information, the label and/or  
9 warnings, would have been different and/or the approval would not have occurred.

10       35. At all times pertinent, agents of Defendants did act in concert to sell and  
11 promote Ortho Evra™.

12       36. Before, during and after Ortho Evra™ was introduced, promoted and sold, key  
13 agents of Defendants who knew or should have known of the dangerous propensities of  
14 Ortho Evra™, went to work for other named Defendants, and continued to introduce,  
15 promote, sell and distribute Ortho Evra™.

16        37. Despite test results indicating an increased risk of thrombotic events, the  
17 warnings associated with Ortho Evra™ ignored those facts.

18        38. Throughout the early years of it's distribution, medical articles and studies  
19 appeared reporting the frequent and common occurrence of clotting and heart problems  
20 associated with women who were on Ortho Evra™, at rates far higher than associated with  
21 other oral contraceptives.

22        39. Defendants knew and or should have known that such reports indicated Ortho  
23 Evra™ was the cause of these problems and that the risks associated with use were far  
24 outweighed by the convenience of the use of a transdermal delivery system with the  
25 formulation of Ortho Evra™.

26 40. Defendants claim that Ortho Evra™ helps prevent pregnancy the same way

1 birth control pills do by preventing ovulation, by thickening the cervical mucus, and by  
2 changing the endometrium to reduce the chance of implantation.

3       41. Unlike birth control pills, the Ortho Evra™ birth control patch is transdermal,  
4 meaning continuous levels of the hormones norelgestromin and ethinyl estradiol (progesterin  
5 and estrogen, respectively) are delivered through the skin into the bloodstream, so that the  
6 amount of hormone delivered is far higher than ordinary oral contraceptives.

7       42. On November 10, 2005, in the face of extreme pressure from the FDA,  
8 Defendants updated the prescribing information for Ortho Evra™ to include a new warning  
9 and provide additional information on the differences between Ortho Evra™ in a weekly  
10 transdermal delivery system and a daily oral delivery system. The new warning states:

11       The pharmacokinetic (PK) profile for the Ortho Evra™ patch  
12 is different from the PK profile for oral contraceptives in that it  
13 has higher steady state concentrations and lower peak  
14 concentrations. AUC and average concentration at steady state  
15 for ethinyl estradiol (EE) are approximately 60% higher in  
16 women using Ortho Evra™ compared with women using an oral  
17 contraceptive containing EE 35 mg. In contrast, peak  
18 concentrations for EE are approximately 25% lower in women  
19 using Ortho Evra™. Inter-subject variability results in increased  
exposure to EE in some women using either Ortho Evra™ or  
oral contraceptives. However, inter-subject variability in women  
using Ortho Evra™ is higher. In general, increased estrogen  
exposure may increase the risk of adverse events. However, it is  
not known whether there are changes in the risk of serious  
adverse events based on the differences in pharmacokinetic  
profiles of EE in women using Ortho Evra™ compared with  
women using oral contraceptives containing 35mg of EE.

20       43. The new label dated November 10, 2005, also contains a new section entitled  
21 "Transdermal versus Oral Contraceptives." In a study of 32 healthy female volunteers, it was  
22 found that the overall exposure for NGMN [norelgestromin] and EE [ethinyl estradiol] (AUC  
23 and Css) was higher in subjects treated with Ortho Evra™ for both Cycle 1 and Cycle 2,  
24 compared to that for the oral contraceptive, while Cmax values were higher in subjects  
25 administered the oral contraceptive. Under steady-state conditions, AUC0-168 and Css,  
26 EE were approximately 55% and 60% higher, respectively, for the transdermal patch, and the

1 Cmax was about 35% higher for the oral contraceptive, respectively. Inter-subject variability  
2 (%CV) for the PK parameters following delivery from Ortho Evra™ was higher relative to  
3 the variability determined from the oral contraceptive.

4       44.     The November 10, 2005 label also provides that in the study of 32 healthy  
5 female volunteers, the percent change in systemic estrogenic activity related to the Sex  
6 Hormone Binding Globulin (SHBG) was higher for Ortho Evra™ users compared to women  
7 taking the oral contraceptive.

8       45.     In the face of the problems associated with the formulation of Ortho Evra™,  
9 Defendants changed the formulation and warnings in the Canadian equivalent of Ortho  
10 Evra™, but did not do the same in the United States.

11       46.     Defendants did knowingly and/or negligently and/or recklessly and/or  
12 maliciously employ qualified and unqualified researchers who falsely and/or negligently  
13 and/or maliciously, ignored the dangers associated with Ortho Evra™ at a time when  
14 Defendants could have avoided injuries sustained by these Plaintiffs.

15       47.     Defendants did employ qualified and unqualified researchers who  
16 systematically ignored the dangers associated with Ortho Evra™ and falsely and/or  
17 negligently and/or recklessly and/or maliciously reported to Defendants, the FDA, health care  
18 providers and the public that the risks associated with Ortho Evra™ were the same as any  
19 other form of hormonal replacement birth control drug.

20       48.     Defendants knew of the significant risk of dental and oral complications caused  
21 by use of Ortho Evra™, but Defendants did not adequately and sufficiently warn consumers,  
22 including Plaintiffs, or the medical community, of such risk.

23       49.     As a direct result, Plaintiffs were prescribed Ortho Evra™ and have been  
24 permanently and severely injured, having suffered serious consequences from the use of  
25 Ortho Evra™. Plaintiffs require and will in the future require ongoing medical care and  
26 treatment.

1       50. Plaintiffs has suffered mental anguish from the knowledge that Plaintiffs will  
2 have life-long complications as a result of the injuries Plaintiffs sustained from the use of  
3 Ortho Evra™.

4       51. Plaintiffs were prescribed and used Ortho Evra™ in a foreseeable manner  
5 pursuant to their respective prescriptions.

6       52. Plaintiffs, as a direct and proximate result of using Ortho Evra™, suffered  
7 severe mental and physical pain and suffering and has sustained permanent injuries and  
8 emotional distress.

9       53. Plaintiffs used Ortho Evra™ which had been provided in a condition that was  
10 substantially the same as the condition in which it was manufactured and sold.

11       54. Plaintiffs would not have used Ortho Evra™ had Defendants properly  
12 disclosed the risks associated with the drug. Alternatively, Plaintiffs would have known  
13 and/or recognized the precursors to thrombolytic and myocardial events, they may have been  
14 able to avoid the clinical manifestation of these problems.

15       55. Defendants, through their affirmative misrepresentations and omissions,  
16 actively concealed from Plaintiffs and their physicians the true and significant risks  
17 associated with taking Ortho Evra™. The running of any applicable Statute of Limitations  
18 has been tolled by reason of Defendants' fraudulent concealment.

19       56. As a result of Defendants' actions, Plaintiffs and prescribing physicians were  
20 unaware, and could not have reasonably known or have learned through reasonable diligence,  
21 that Plaintiffs had been exposed to the risk identified in this complaint, and that those risks  
22 were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

23       57. Defendants actions amounted to overpromotion.

24       58. Defendants actions do not meet the criteria necessary to overcome the  
25 "Reasonable Expectations Doctrine".

26

**FIRST CAUSE OF ACTION**  
**(Negligence)**

59. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

60. Defendants owed Plaintiffs, and other consumers, a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and/or selling Ortho Eyratm.

61. Defendants failed to exercise due care under the circumstances and therefore breached this duty by:

- a. Failing to properly and thoroughly test Ortho Evra™ before releasing the drug to market;
  - b. Failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of Ortho Evra™;
  - c. Failing to conduct sufficient post-market testing and surveillance of Ortho Evra™;
  - d. Designing, manufacturing, marketing, advertising, distributing, and selling Ortho Evra™ to consumers, including Plaintiffs, without an adequate warning of the significant and dangerous risks of Ortho Evra™ and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
  - e. Failing to exercise due care when advertising and promoting Ortho Evra™; and,
  - f. Negligently continuing to manufacture, market, advertise, and distribute Ortho Evra™ after Defendants knew or should have known of its adverse effects.

62. As a direct and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered serious personal injuries. In addition, Plaintiffs required and will continue to require healthcare and services. Plaintiffs have incurred and will continue to incur medical and related expenses. Plaintiffs also have suffered and will

1 continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life,  
2 increased risk of premature death, aggravation of preexisting conditions and activation of  
3 latent conditions, and other losses and damages. Plaintiffs have incurred and will continue  
4 to incur direct medical losses and costs include care for hospitalization, physician care,  
5 monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue  
6 to incur mental and physical pain and suffering. Plaintiffs have suffered loss of wages and  
7 wage-earning capacity.

8       63. Defendants' conduct as described above was committed with knowing,  
9 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights  
10 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages  
11 so as to punish Defendants and deter them from similar conduct in the future.

12 WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
13 compensatory damages, and exemplary and punitive damages together with interest, the costs  
14 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

**SECOND CAUSE OF ACTION**  
**(Products Liability)**

64. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

18 65. Defendants manufactured, sold, distributed, marketed, and/or supplied Ortho  
Evra™ in a defective and unreasonably dangerous condition to consumer, including  
19 Plaintiffs.

21 66. Defendants designed, manufactured, sold, distributed, supplied, marketed,  
22 and/or promoted Ortho Evra™, which was expected to reach and did in fact reach  
23 consumers, including Plaintiffs, without substantial change in the condition in which it was  
manufactured and sold by Defendants.

24 67. Plaintiffs used Ortho Evra™ as prescribed and in a manner normally intended,  
25 recommended, promoted and marketed by Defendants.

1       68. Ortho Evra™ failed to perform safely when used by ordinary consumers,  
2 including Plaintiffs, including when it was used as intended and in a reasonably foreseeable  
3 manner.

4       69. Ortho Evra™ was defective in its design and was unreasonably dangerous in  
5 that its risks exceeded the benefits associated with its design or formulation.

6       70. Ortho Evra™ was defective in design or formulation in that it posed a greater  
7 likelihood of injury than other similar medications and was more dangerous than an ordinary  
8 consumer could reasonably foresee or anticipate.

9       71. Ortho Evra™ was defective in its design and was unreasonably dangerous in  
10 that it neither bore nor was packaged with nor accompanied by warnings adequate to alert  
11 consumers, including Plaintiffs, of the risks described herein, including, but not limited to,  
12 the risk of thromboembolic and/or thrombolytic events.

13       72. Although Defendants knew or should have known of the defective nature of  
14 Ortho Evra™, it continued to design, manufacture, market, and sell Ortho Evra™ so as to  
15 maximize sales and profits at the expense of the public health and safety. By so acting,  
16 Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by  
17 Ortho Evra™.

18       73. Plaintiffs could not, through the exercise of reasonable care, have discovered  
19 Ortho Evra™'s defects or perceived the dangers posed by the drug.

20       74. As a direct and proximate consequence of Defendants' conduct, Plaintiffs  
21 suffered serious personal injuries. In addition, Plaintiffs required and will continue to require  
22 healthcare. Plaintiffs have incurred and will continue to incur medical and related expenses.  
23 Plaintiffs also have suffered and will continue to suffer diminished capacity for the  
24 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation  
25 of preexisting conditions and activation of latent conditions, and other losses and damages.  
26 Plaintiffs' direct medical losses and costs include care for hospitalization, physician care,

monitoring, treatment, medications, and supplies. Plaintiffs incurred and will continue to incur mental and physical pain and suffering. Plaintiffs suffered loss of wages and wage-earning capacity.

4 75. Defendants' conduct as described above was committed with knowing,  
5 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights  
6 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages  
7 so as to punish Defendants and deter them from similar conduct in the future.

8 WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
9 compensatory damages, and exemplary and punitive damages together with interest, the costs  
10 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

**THIRD CAUSE OF ACTION**  
**(Breach of Express Warranty)**

76. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

77. Defendants expressly represented to Plaintiffs and other consumers and the  
14 medical community that Ortho Evra™ was safe and fit for its intended purposes, that it was  
15 of merchantable quality, that it did not produce any dangerous side effects, and that it was  
16 adequately tested.

17        78. Ortho Evra™ does not conform to Defendants' express representations because  
18 it is not safe, has numerous and serious side effects, and causes severe and permanent  
19 injuries.

21 79. At all relevant times Ortho Evra™ did not perform as safely as an ordinary  
consumer would expect, when used as intended or in a reasonably foreseeable manner.

23 80. Plaintiffs, other consumers, and the medical community relied upon  
Defendants' express warranties.

24       81. As a direct and proximate result of Defendants' actions, Plaintiffs suffered  
25 serious personal injuries. In addition, Plaintiffs required and will continue to require

1 healthcare and services. Plaintiffs incurred and will continue to incur medical and related  
2 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the  
3 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation  
4 of preexisting conditions and activation of latent conditions, and other losses and damages.  
5 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include  
6 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.  
7 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.  
8 Plaintiffs have suffered loss of wages and wage-earning capacity.

9       82. Defendants' conduct as described above was committed with knowing,  
10 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights  
11 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages  
12 so as to punish Defendants and deter them from similar conduct in the future.

13 WHEREFORE, Plaintiffs demand judgment against Defendants and seeks  
14 compensatory damages, and exemplary and punitive damages together with interest, the costs  
15 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

**FOURTH CAUSE OF ACTION  
(Breach of Implied Warranty)**

83. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

84. Defendants manufactured, distributed, advertised, promoted and sold Ortho

Evra™

21 85. At all relevant times, Defendants knew of the use for which Ortho Evra™ was  
22 intended and impliedly warranted the product to be of merchantable quality and safe and fit  
for such use.

23 86. Defendants were aware that consumers, including Plaintiffs, would use Ortho  
24 Evra™ for treatment of osteoporosis and for other purposes.

87. Plaintiffs and the medical community reasonably relied upon the judgment and

1 sensibility of Defendants to sell Ortho Evra™ only if it was indeed of merchantable quality  
2 and safe and fit for its intended use.

3       88. Defendants breached their implied warranty to consumers, including Plaintiffs;  
4 Ortho Evra™ was not of merchantable quality or safe and fit for its intended use.

5       89. Consumers, including Plaintiffs, and the medical community, reasonably relied  
6 upon Defendants' implied warranty for Ortho Evra™.

7       90. Ortho Evra™ reached consumers without substantial change in the condition  
8 in which it was manufactured and sold by Defendants.

9       91. As a direct and proximate result of Defendants' actions, Plaintiffs suffered  
10 serious personal injuries. In addition, Plaintiffs required and will continue to require  
11 healthcare and services. Plaintiffs incurred and will continue to incur medical and related  
12 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the  
13 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation  
14 of preexisting conditions and activation of latent conditions, and other losses and damages.  
15 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include  
16 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.  
17 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.  
18 Plaintiffs have suffered loss of wages and wage-earning capacity.

19       92. Defendants' conduct as described above was committed with knowing,  
20 conscious, wanton, willful, and deliberate disregard for the value of human life and rights  
21 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages  
22 so as to punish Defendant and deter it from similar conduct in the future.

23       **WHEREFORE**, Plaintiffs demand judgment against Defendants and seek  
24 compensatory damages, and exemplary and punitive damages together with interest, the costs  
25 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

26 / / /

**FIFTH CAUSE OF ACTION**  
**(Fraudulent Misrepresentation)**

93. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

94. Defendants made fraudulent misrepresentations with respect to Ortho Evra™ in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Ortho Evra™ had been tested and found to be safe and effective for the treatment and prevention of osteoporosis; and

b. Defendants represented that Ortho Evra™ was safer than other alternative medications.

95. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Ortho Evra™ to consumers, including Plaintiffs, and the medical community.

96. The representations were made by Defendants with the intent that doctors and patients, including Plaintiffs, rely upon them.

97. Defendants' representations were made with the intent of defrauding and deceiving Plaintiffs, other consumers, and the medical community to induce and encourage the sale of Ortho Evra™.

98. Plaintiffs' doctors, and others relied upon the representations.

99. Defendants' fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety and welfare of consumers, including Plaintiffs.

100. As a direct and proximate result of Defendants' actions, Plaintiffs suffered serious personal injuries. In addition, Plaintiffs required and will continue to require

1 healthcare and services. Plaintiffs incurred and will continue to incur medical and related  
2 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the  
3 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation  
4 of preexisting conditions and activation of latent conditions, and other losses and damages.  
5 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include  
6 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.  
7 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.  
8 Plaintiffs have suffered loss of wages and wage-earning capacity.

9       101. Defendants' conduct as described above was committed with knowing,  
10 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights  
11 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages  
12 so as to punish Defendant and deter it from similar conduct in the future.

13 WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
14 compensatory damages, and exemplary and punitive damages together with interest, the costs  
15 of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

**SIXTH CAUSE OF THE ACTION  
(Fraudulent Concealment)**

102. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

18       103. Defendants made fraudulent misrepresentations with respect to Ortho Evra™  
19       in the following particulars:

a. Defendants represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Ortho Evra™ was safe and fraudulently withheld and concealed information about the substantial risks of using Ortho Evra™; and

b. Defendants represented that Ortho Evra™ was safer than other alternative medications and fraudulently concealed information which demonstrated that

1 Ortho Evra™ was not safer than alternatives available on the market.

2       104. Defendants had sole access to material facts concerning the dangers and  
3 unreasonable risks of Ortho Evra™.

4       105. The concealment of information by Defendants about the risks of Ortho Evra™  
5 was intentional, and the representations made by Defendants were known by Defendants to  
6 be false.

7       106. The concealment of information and the misrepresentations about Ortho  
8 Evra™ were made by Defendants with the intent that doctors and patients including  
9 Plaintiffs, rely upon them.

10      107. Plaintiffs' doctors, and others relied upon the representations and were unaware  
11 of the substantial dental and oral risks of Ortho Evra™ which Defendants concealed from  
12 Plaintiffs' doctors and Plaintiffs.

13      108. As a direct and proximate result of Defendants' actions, Plaintiffs suffered  
14 serious personal injuries. In addition, Plaintiffs required and will continue to require  
15 healthcare and services. Plaintiffs incurred and will continue to incur medical and related  
16 expenses. Plaintiffs also suffered and will continue to suffer diminished capacity for the  
17 enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation  
18 of preexisting conditions and activation of latent conditions, and other losses and damages.  
19 Plaintiffs have incurred, and will continue to incur, direct medical losses and costs include  
20 care for hospitalization, physician care, monitoring, treatment, medications, and supplies.  
21 Plaintiffs incurred and will continue to incur mental and physical pain and suffering.  
22 Plaintiffs have suffered loss of wages and wage-earning capacity.

23      109. Defendants' conduct as described above was committed with knowing,  
24 conscious, wanton, willful, and deliberate disregard for the value of human life and the rights  
25 and safety of consumers such as Plaintiffs, thereby entitling Plaintiffs to punitive damages  
26 so as to punish Defendant and deter it from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

### **SEVENTH CAUSE OF ACTION**

### **(Equitable Relief)**

### **(Medical Monitoring Program and Proper Labeling)**

6 110. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

7       111. As a direct and proximate result of Defendants' acts, Plaintiffs face an  
8 increased susceptibility to injuries as described herein. The irreparable threat to their health  
9 can only be mitigated by the creation of a medical monitoring fund to provide for a medical  
10 monitoring program, including: notifying Plaintiffs and subclasses of the defects and the  
11 potential medical harm; funding of a program for the surgical treatment of thrombolytic  
12 events; funding a study for the long term effects of Ortho Evra™ upon Plaintiffs; gathering  
13 and forwarding to treating physicians information relating to the diagnosis and treatment of  
14 injuries which may result from the product; and funding for diagnosis and preventative  
15 medical treatment, particularly dental and oral monitoring.

16 112. Plaintiffs have no adequate remedy in law in that monetary damages alone do  
17 not compensate for the insidious and continuing nature of the harm to them, and only a  
18 medical monitoring program which notified Plaintiffs and aids in correcting the problems can  
19 prevent the greater harms which may not occur immediately and which may be preventable,  
20 if proper research is conducted and the health risk are diagnosed and treated before they  
21 occur or become worse.

22 113. Plaintiffs suffered irreparable harm as alleged herein and, in the absence of  
23 equitable relief, Plaintiffs will suffer further irreparable harm such as death and severe and  
24 debilitating injuries from continued retention of the defective drug. Without a medical  
25 monitoring program, Plaintiffs might not receive prompt medical care which could prolong  
26 their productive lives, increase prospects for improvement and minimize disability.

1       114. Additionally, Defendants have refused to fully abide by the FDA's request to  
2 amend the Ortho Evra™ product labeling information to warn physicians and patients about  
3 the risk of thrombolytic events. Because of their failure, prescribing physicians are unable  
4 to warn patients to be aware of precursor symptoms which, if properly observed and reported  
5 to the physician, could result in discontinuation of Ortho Evra™ therapy and the prevention  
6 or mitigation of serious injury, including thrombolytic events. This Court should use its  
7 equitable powers, in the interest of the public safety and in order to make sure that  
8 prescribing physicians have a complete understanding of the risks associated with Ortho  
9 Evra™ to require Defendant to change its label in a format approvable by the FDA to  
10 adequately warn physicians and Ortho Evra™ patients about the risk of thrombolytic events,  
11 and steps which can be taken to prevent or mitigate its occurrence.

12 WHEREFORE, Plaintiffs demand judgment against Defendants and seeks equitable  
13 relief in the form of a medical monitoring program this Court's order that Defendants change  
14 the labeling of Ortho Evra™ to appropriately warn of the risk of thromboembolic and/or  
15 thrombolytic events.

**EIGHTH CAUSE OF ACTION**  
(Violation of Business & Profession Code Section 17200)

115. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

116. Plaintiffs are informed and believe and allege that Defendants, by the acts and  
19 misconduct alleged herein, violated Business and Professions Code sections 17200.

117. California Business & Professions Code Section 17200 provides that unfair  
competition shall mean and include "all unlawful, unfair or fraudulent business practices and  
unfair, deceptive, untrue or misleading advertising."

118. The acts and practices described herein were and are likely to mislead the  
general public and therefore constitute unfair business practices within the meaning of  
Business & Professions Code Section 17200. The acts and untrue and misleading advertising

1 set forth in presiding paragraphs are incorporated by reference and are, by definition,  
2 violations of Business & Professions Code Section 17200. This conduct includes, but is not  
3 limited to:

4           a.     Representing to Plaintiffs, Plaintiffs's physicians and the general public  
5 that Ortho Evra™ was safe, fit and effective for human consumption, knowing that said  
6 representations were false, and concealing from the Plaintiffs, Plaintiffs' physicians and the  
7 general public that Ortho Evra™ has a serious propensity to cause injuries to users;

8           b.     Engaging in advertising programs designed to create the image,  
9 impression and belief by consumers, physicians and others that the use of Ortho Evra™ was  
10 safe for human use, had fewer side effects and adverse reactions than other methods for  
11 osteoporosis, constituted a convenient, safe form for treating osteoporosis and would not  
12 interfere with daily life, even though the Defendants knew these to be false, and even though  
13 the Defendants had no reasonable grounds to believe them to be true;

14           c.     Purposely downplaying and understating the health hazards and risks  
15 associated with Ortho Evra™; and

16           d.     Issuing promotional literature deceiving potential users of Ortho Evra™  
17 by relaying positive information and manipulating statistics to suggest widespread  
18 acceptability, while downplaying the known adverse and serious health effects and  
19 concealing material relevant information regarding the safety of Ortho Evra™.

20       119. These practices constitute unlawful, unfair and fraudulent business acts or  
21 practices, within the meaning of California Business & Professions Code Section 17200, as  
22 well as unfair, deceptive, untrue and misleading advertising as prohibited by California  
23 Business & Professions Code Section 17500, as set forth herein.

24       120. The unlawful, unfair and fraudulent business practices of Defendants described  
25 above present a continuing threat to members of the public in that Defendants continue to  
26 engage in the conduct described therein.

1 121. As a result of their conduct described above, Defendants have been unjustly  
2 enriched. Specifically, Defendants have been unjustly enriched by receipt of hundreds of  
3 millions of dollars in ill-gotten gains from the sale and prescription of Ortho Evra™ in  
4 California, and other states, sold in large part as a result of the acts and omissions described  
5 herein.

6 122. Because of the fraudulent misrepresentations made by Defendants as detailed  
7 above, and the inherently unfair practice of committing a fraud against the Plaintiffs and  
8 public by intentionally misrepresenting and concealing material information; the acts of  
9 Defendant described herein constitute unfair or fraudulent business practices.

10       123. Plaintiffs, pursuant to California Business & Professions Code Section 17203,  
11 seek an order of this court compelling the Defendant to provide restitution, and to disgorge  
12 the monies collected and profits realized by Defendants, and each of them, as a result of their  
13 unfair business practices.

14 124. Defendants' acts were willful, wanton, reckless and fraudulent; hence,  
15 Plaintiffs are entitled to exemplary damages, inter alia.

16 WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
17 compensatory damages, disgorgement, restitution, and exemplary and punitive damages  
18 together with interest, the costs of suit, attorneys' fees and such other and further relief as the  
19 Court deems just and proper.

**NINTH CAUSE OF ACTION**  
**(Violation of Business & Profession Code Section 17500)**

125. Plaintiffs restate the allegations set forth above as it fully rewritten herein.

23 126. Plaintiffs are informed and believe and thereon allege that Defendants, by the  
acts and misconduct alleged herein, violated Business & Professions Code Section 17500.

24  
25 127. Plaintiffs hereby seek restitution, as well as and punitive damages against  
Defendants for their violations of section 17500

1       128. California Business & Professions Code section 17500 provides that it is  
2 unlawful for any person, firm, corporation or association to dispose of property or perform  
3 services, or to induce the public to enter into any obligation relating thereto, through the use  
4 of untrue or misleading statements.

5       129. At all times herein mentioned, Defendants have committed the acts of  
6 disseminating untrue and misleading statements as defined by Business & Professions Code  
7 Section 17500 by engaging in the following acts and practices with intent to induce members  
8 of the public to purchase and use Ortho Evra™;

9           a.      Representing to Plaintiffs, Plaintiffs' physicians and the general public  
10 that Ortho Evra™ was safe, fit and effective for human consumption, knowing that said  
11 representations were false, and concealing from the Plaintiffs, Plaintiffs' physicians and the  
12 general public that Ortho Evra™ have a serious propensity to cause injuries to users;

13           b.      Engaging in advertising programs designed to create the image,  
14 impression and belief by consumers, physicians and others that the use of Ortho Evra™ was  
15 safe for human use, had fewer side effects and adverse reactions than other methods for  
16 treating osteoporosis, constituted a convenient, safe form for treating osteoporosis and would  
17 not interfere with daily life, even though the Defendants knew these to be false, and even  
18 though the Defendants had no reasonable grounds to believe them to be true;

19           c.      Purposely downplaying and understating the health hazards and risks  
20 associated with Ortho Evra™; and

21           d.      Issuing promotional literature deceiving potential users of Ortho Evra™  
22 by relaying positive information and manipulating statistics to suggest widespread  
23 acceptability, while downplaying the known adverse and serious health effects and  
24 concealing material relevant information regarding the safety of Ortho Evra™.

25       130. The foregoing practices constitute false and misleading advertising within the  
26 meaning of California Business & Professions Code Section 17500.

1        131. As a result of its false and misleading statements described above, Defendants  
2 have been and will be unjustly enriched. Specifically, Defendants have been unjustly  
3 enriched by receipt of hundreds of millions of dollars from the sale and prescription of Ortho  
4 Evra™ in California and other states, sold in large part as a result of the false or misleading  
5 statements described herein.

6 132. Pursuant to California Business & Professions Code Section 17535, Plaintiffs  
7 seeks an order of this court compelling the Defendants to provide restitution, and to disgorge  
8 the monies collected and profits realized by Defendants, and each of them, as a result of their  
9 unfair business practices, and injunctive relief calling for Defendants to cease such unfair  
10 business practices in the future.

11 WHEREFORE, Plaintiffs demand judgment against Defendants and seek  
12 compensatory damages, disgorgement, restitution, and exemplary and punitive damages  
13 together with interest, the costs of suit, attorneys' fees and such other and further relief as the  
14 Court deems just and proper.

**TENTH CAUSE OF ACTION**  
**(Loss of Consortium).**

133. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

17 134. Plaintiffs Donny Wright and Donny Peters, who did not use Ortho Evra™,  
18 bring this cause of action for loss of consortium.

19       135. By reason of the injuries sustained by Plaintiffs Meloney Wright and Veronique  
20 Peters, who did use Ortho Evra™, Plaintiffs Donny Wright and Donny Peters, have been and  
21 will continue to be deprived of consortium, society, comfort, protection, and service, thereby  
22 causing and continuing to cause grief, sorrow, mental anguish, emotional distress and pain  
23 and suffering.

WHEREFORE, Plaintiffs Donny Wright and Donny Peters demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together

1 with interest, the costs of suit, attorneys' fees and such other and further relief as the Court  
2 deems just and proper.

**ELEVENTH CAUSE OF ACTION  
(Punitive Damages)**

136. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

137. Defendants have repeatedly engaged in a pattern of conduct of deliberately avoiding FDA recommendations as to public hazards which should be warned about.

138. Defendants' acts were willful and malicious in that Defendants' conduct was carried on with a conscious disregard for the safety and rights of Plaintiffs and all others taking Ortho Evra™. Defendants' unconscionable conduct thereby warrants an assessment of exemplary and punitive damages in an amount appropriate to punish Defendants and deter similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and further relief as the Court deems just and proper.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and/or severally, as follows:

- a. For general damages in an amount to be proven at the time of trial;
  - b. For special damages in an amount to be proven at time of trial;
  - c. For exemplary and punitive damages in an amount to be proven at the time of trial, and sufficient to punish Defendant or to deter Defendant and others from repeating the injurious conduct alleged herein;
  - d. For prejudgment and post-judgment interest on the above general and special damages;
  - e. For disgorgement of profits;

- 1 f. For restitution;
- 2 g. For costs and attorneys' fees; and
- 3 h. All other relief that Plaintiffs may be entitled to at equity or at law, including
- 4 but not limited to the funding of a medical monitoring program and compelling Defendants
- 5 to adequately warn about the risk of thrombolytic and other adverse events, associated with
- 6 use of Ortho Evra™.

**DEMAND FOR JURY TRIAL**

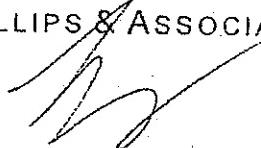
Plaintiffs demand a trial by jury on all claims so triable in this action.

Dated: February 9, 2007

Respectfully submitted,

PHILLIPS & ASSOCIATES

By:

  
Robert F. Clarke, Esq.  
3030 North Third Street, Suite 1100  
Phoenix, Arizona 85012  
Attorneys for Plaintiffs

26

CASE NUMBER: CGC-07-460481 MELONEY WRIGHT VS. ORTHO-MCNEIL CORPORATION

**NOTICE TO PLAINTIFF**

A Case Management Conference is set for

**DATE:** JUL-20-2007

**TIME:** 9:00AM

**PLACE:** Department 212  
400 McAllister Street  
San Francisco, CA 94102-3680

All parties must appear and comply with Local Rule 3.

CRC 3.725 requires the filing and service of a case management statement form CM-110 no later than 15 days before the case management conference.

However, it would facilitate the issuance of a case management order **without an appearance** at the case management conference if the case management statement is filed, served and lodged in Department 212 twenty-five (25) days before the case management

Plaintiff must serve a copy of this notice upon each party to this action with the summons and complaint. Proof of service subsequently filed with this court shall so state.

**ALTERNATIVE DISPUTE RESOLUTION POLICY REQUIREMENTS**

IT IS THE POLICY OF THE SUPERIOR COURT THAT EVERY CIVIL CASE PARTICIPATE IN EITHER MEDIATION, JUDICIAL OR NON-JUDICIAL ARBITRATION, THE EARLY SETTLEMENT PROGRAM OR SOME SUITABLE FORM OF ALTERNATIVE DISPUTE RESOLUTION PRIOR TO A MANDATORY SETTLEMENT CONFERENCE OR TRIAL. (SEE LOCAL RULE 4)

Plaintiff must serve a copy of the Alternative Dispute Resolution Information Package on each defendant along with the complaint. All counsel must discuss ADR with clients and opposing counsel and provide clients with a copy of the Alternative Dispute Resolution Information Package prior to filing the Case Management Statement.

[DEFENDANTS: Attending the Case Management Conference does not take the place of filing a written response to the complaint. You must file a written response with the court within the time limit required by law. See Summons.]

Superior Court Alternative Dispute Resolution Coordinator  
400 McAllister Street, Room 103  
San Francisco, CA 94102  
(415) 551-3876

See Local Rules 3.6, 6.0 C and 10 D re stipulation to commissioners acting as temporary judges